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09/910,054	07/23/2001	Mayumi Tomikawa	522.1921D	4839

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EXAMINER

MORAN, MARJORIE A

ART UNIT	PAPER NUMBER
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1631

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DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/910,054	TOMIKAWA ET AL.
	Examiner	Art Unit
	Marjorie A. Moran	1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 24 July 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 5-11 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 5-11 and 21 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 23 July 2001 is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2</u> | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

Applicant is thanked for bringing the preliminary amendment to the examiner's attention. The amendment of 7/23/01 has been entered. Claims 5-11 and 21 are pending. As the product of claim 21 is an apparatus comprising means for performing method steps identical to those of claim 5, it would not pose an undue burden on the examiner to search for the product of claim 21 together with the method of claims 5-11. For this reason, claim 21 is rejoined with claims 5-11.

Applicant's election of Group I, claims 5-11 in Paper No. 4, filed 7/24/03, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). As claim 21 has been rejoined with those of Group I, claim 21 is also considered elected.

An action on the merits of claims 5-11 and 21 follows.

Priority

Applicant is requested to update the status of priority application(s) disclosed on the first page of the specification.

Information Disclosure Statement

The information disclosure statement filed 7/23/01 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because all of the references listed therein are not identified by source of publication and publication date. It has been placed in the application file, but not all the information referred to therein has been considered as to the merits. Reference AV by Tomioka et al. is only identified by authors, title of the article, and pages. The

examiner could not find any indication on the reference itself as to what journal, book, etc. the reference was published in, nor could the examiner find a year of reference. All references considered by the examiner have been initialed. Reference AV has been crossed out to indicate non-consideration.

Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Specification

The disclosure is objected to because of the following: the specification describes a Figure 20A and 20B; however, there is no Figure labeled "Figure 20A" or "Figure 20B" or merely "Figure 20", nor are there any drawings/figures which correspond to the description of the specification. The numbering of the Figures "skips" from 19 to 21; however, the page numbers of the figures is sequential (i.e. page 19/45 corresponds to Figure 19 while page 20/45 corresponds to Figure 21). Appropriate correction is required. Applicant is reminded that any amendment must be fully supported by the originally filed disclosure and is cautioned to avoid inadvertent insertion of new matter into the specification or drawings.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

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Claims 5-11 and 21 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. All of the steps recited in claims 5-11 are steps of manipulating mathematical data, equivalent to mental processes. Applicant is reminded that mental processes are not statutory subject matter under 35 USC 101. The claimed method is not restricted to be a computer-implemented method; however, the specification indicates that the inventive method is intended to be one implemented by a computer. A computer-implemented method comprising only steps of data manipulation may be statutory when the result produced is concrete, tangible and useful. The method of claims 5-11 does not produce a concrete, tangible and useful result, as elucidated below. Claim 21 is directed to an apparatus comprising means for performing method steps identical to those of claim 5. No structural limitations of the apparatus are recited in the claim. As the apparatus is therefore limited only by its function, and that function does not produce a concrete, tangible and useful result, the apparatus of claim 21 is not statutory. See below.

As set forth in MPEP 2106.IV.B:

"In practical terms, claims define nonstatutory processes if they:

- consist solely of mathematical operations without some claimed practical application (i.e., executing a "mathematical algorithm"); or
- simply manipulate abstract ideas, e.g., a bid (Schrader, 22 F.3d at 293-94, 30 USPQ2d at 1458-59) or a bubble hierarchy (Warmerdam, 33 F.3d at 1360, 31 USPQ2d at 1759), without some claimed practical application."

And at MPEP 2106.IV.B.2(b) (ii):

"A claim is limited to a practical application when the method, as claimed, produces a concrete, tangible and useful result; i.e., the method recites a step or act of

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producing something that is concrete, tangible and useful. See AT &T, 172 F.3d at 1358, 50 USPQ2d at 1452. Likewise, a machine claim is statutory when the machine, as claimed, produces a concrete, tangible and useful result (as in State Street, 149 F.3d at 1373, 47 USPQ2d at 1601) and/or when a specific machine is being claimed (as in Alappat, 33 F.3d at 1544, 31 USPQ2d at 1557 (in banc). For example, a computer process that simply calculates a mathematical algorithm that models noise is nonstatutory.

The “practical application” toward which the claims are apparently directed is the analysis of a three dimensional structure. However, the claims do not actually recite any step of analysis. The steps actually recited in the claims merely result in a calculation of a distance between elements. The result of this mathematical manipulation, per se, is not a concrete, tangible, and useful result and the “immediate” usefulness (or utility) of the result is not apparent. See below regarding utility. It does not appear that the claimed method steps actually provide a “practical application in the art.” As the claims merely recite an apparatus and steps for mathematically manipulating data, and the claimed method does not produce a concrete, tangible and useful result, the claims do not recite statutory subject matter.

Further with regard to claim 21,

It is noted that a claim may be statutory when it identifies the physical structure of an item of manufacture in terms of its hardware, or a hardware and software combination. Claim 21 does not recite any physical or hardware limitations, as set forth above. It is also noted that a claim to a product which has a practical application in the arts may be statutory; e.g. a computer comprising a program which produces a concrete, tangible, and useful result, as decided in Alappat (31 USPQ2d 1557) and State Street (47 USPQ2d 1601). As set forth above, the claimed method does not produce a concrete, tangible and useful result, therefore the

apparatus for performing such a method would not have a practical application in the arts, and is not statutory.

Claims 5-11 and 21 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. The claims recite a method and apparatus for analyzing three dimensional structures. As set forth above, the claims do not recite any specific steps or means of analysis. The claimed method steps result in calculation of a root mean square distance between elements belonging to two point sets. These point sets are not limited to be from two different structures, therefore the claims encompass comparison of point sets from different areas of domains of the same compound or molecule. The specification does not disclose a utility for comparing different parts of the same compound or molecule and none is apparent. The claim also encompass point sets from two different structures, whereupon the method may presumably be used to compare different compounds or molecules. A "use" of the inventive method for comparing a different compounds (e.g. enzymes) is set forth and exemplified in the specification on pages 46-52. However, while the example of the specification provides results of the comparison, there is no disclosure for what one skilled in the art would, in fact, use this information for. The specification also asserts, on page 5, that the inventive method may be used to extract motifs. However, an extraction of motifs requires a determination of a degree of similarity between two proteins/sequences/structures. The claims do not recite any step or limitation for determining a degree of similarity. Merely elucidating how far apart elements of compounds are is not an indication that the compounds are, in fact, similar enough to identify the elements as comprising (presumable conserved) motifs, or are different, such that the elements can be eliminated from further consideration/comparison. The claims do not identify any particular compounds for comparison. With no knowledge of identity, function, etc. of the

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structures being compared, nor any determination of a degree of similarity between two structures, the claims do not provide an "immediately useful" result. According to MPEP 2107.01 and as set forth in *Brenner v. Manson* (148 USPQ 689 (1966)) and *In re Ziegler* (26 USPQ2d 1600), a "useful invention" is one wherein the "usefulness" is "immediately apparent to those familiar with the technological field of the invention. As further set forth in MPEP 2107.01, a "use" to do further research, or assaying for or identifying a compound which itself has no, or an unknown utility, is not considered a "substantial utility" under 35 USC 101. As the structures being "assayed" are unknown/not identified in the claim, their utility is unknown. More information and/or further research would be required by one skilled in the art to know what to do/how to use the results of the claimed method and apparatus, as set forth above. For these reasons, the claims lack utility.

Claims 5-11 and 21 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-11 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not

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described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an ENABLEMENT rejection.

The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are the quantity of experimentation; the amount of direction or guidance presented in the specification; the presence or absence of working examples; the nature of the invention; the state of the prior art; the level of skill of those in the art; predictability or unpredictability of the art; and the breadth of the claims.

A method or apparatus comprising a step or means for generating a combination of correspondence satisfying a restriction condition, as recited in claims 5 and 21, is not enabled as neither the specification nor prior art provide guidance for how to determine if a combination of correspondence "satisfies" a restriction condition. The instant specification discloses/exemplifies on pages 27 et seq. Various methods of analyzing three dimensional structures. The specification admits on page 29 that merely comparing two data sets (i.e. merely generating a "combination of correspondence" between two data sets) renders it "nearly impossible" to effect a calculation (of rmsd?) since so many combination are possible. The disclosure of the specification, therefore, indicates that some sort of "restriction" is necessary in order to enable the inventive method. Page 30 then discloses that an "optimum combination" must be generated "in view of" a geometric relationship within the data sets, a threshold value condition, and an attribute of points. Following pages exemplify "ordering" points, refining candidates based on a distance relationship, on angle relationships, or on distances and angles from a center of gravity, and using a threshold value condition. Nowhere does the specification teach how to determine if these restriction "conditions" are met or "satisfied" by a combination of correspondence (i.e. comparison of data). Rather, it appears that the restriction conditions of the specification are used to compare data sets, or create combinations of correspondence. There is no disclosure for how to determine what conditions of a restriction condition must be

met in order to determine if a particular combination (comparison) "satisfies" the restriction condition.

Figures 15 and 17 comprise flow charts which appear to correspond, at least in part, with the claimed method and apparatus. These Figures contain a box asking if a previous step "satisfies a restriction condition?" but neither Figure sets forth any step or means for determining what condition are required in order to determine a "yes" or "no" answer. Figures 36 and 37 comprise flow charts which appear to reflect generating a correspondence of data based on restriction conditions similar to those disclosed in the specification, and disclose particular equations for selecting data from a single data set BEFORE determining a correspondence with a second data set. The claims specifically recite generating a combination of correspondence satisfying a restriction condition BETWEEN elements of a first set and elements of a second set (of data), therefore Figures 36 and 37 do not appear to be a teaching for how to perform the claimed method or how to use the claimed apparatus.

The prior art of PANTOLIONO (IDS ref: US patent 4,853,871) teaches a method for analyzing and comparing three dimensional structures using 3D coordinates and calculation of root mean squares to determine fit; i.e. distance (col. 8, lines 32-65), but does not teach that restriction condition must be met or satisfied in order to generate the comparison and/or perform the root mean square calculation.

The level of skill in the art is considered to be high. However, given the lack of guidance in either the specification or the prior art for how to determine whether a combination of correspondence between two point sets meets or satisfies a restriction condition, and as one skilled in the art would be required to guess at the parameters necessary to perform such a determination or calculation, it would require undue experimentation by one skilled in the art to

generate a combination of correspondence satisfying a restriction condition. For these reasons, the claims are not enabled.

Claim Rejections - 35 USC § 112, 2nd paragraph

Claims 5-11 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites a method for analyzing three-dimensional structures, but does not recite any step of analysis. Similarly , claim 21 recites an apparatus for analyzing three-dimensional structures, but does not recite any means for analysis. The claims recite steps and means for mathematical manipulation of data; however, data manipulation is not necessarily a analysis of a structure. Analysis generally implies decision making or determination of value for the data analyzed (i.e. one usually formulates a conclusion based on an analysis). As the claims do not clearly recite any step or means for analysis, and the method steps and means claimed do not appear to encompass analysis, it is unclear what method and apparatus applicant actually intends, and the claims are indefinite.

Claims 5 and 21 recite generating a combination of correspondence "satisfying" a restriction condition. As set forth above, the specification does not disclose what requirements must be met in order for a combination of correspondence to "satisfy" a restriction condition. The claims do not recite any such requirements. As the metes and bounds intended by applicant with regard to "satisfaction" of a restriction condition are not defined by the specification or in the claims, applicants intended limitations are unclear and the claims are indefinite.

Conclusion

Claims 5-11 and 21 are rejected; the specification is objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3524.

Marjorie A. Moran
MARJORIE MORAN
PATENT EXAMINER

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